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Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,474,787

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,474,787 issued October 2, 1984, which claims the human drug product Tilade, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be five years.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of August 10, 1993. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (844) + 2,130 \\ &= 2,572 \text{ days}\end{aligned}$$

Since the regulatory review period began June 8, 1983, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on June 8, 1983, up to the issuance of the patent on October 2, 1984, is 481 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $1,365 - 481 = 844$  days. No determination of a lack of due diligence was made.

The five year limitation of 35 USC § 156(g)(6)(A) applies in the present situation because the patent was issued after the date of enactment (September 24, 1984) of 35 USC § 156. Since the period of extension calculated under 35 USC § 156(c) for the patent cannot exceed five years under 35 USC § 156(g)(6)(A), the period of extension will be for five years.

The 14 year exception of 35 USC § 156(c)(3) does not operate to further reduce the period determined above.

A single request for reconsideration of this final determination as the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,474,787 a certificate of extension, under seal, for a period of five years.

Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,474,787
Granted:	October 2, 1984
Applicant:	Hugh Cairns et al.
Owner of Record:	Fisons plc
Title:	7,6 DIOXO-4H, 6H-PYRANO [3,2-g] QUINOLINE DICARBOXYLIC ACIDS AND ANTI-ALLERGIC USE THEREOF
Classification:	514/291
Product Trade Name:	Tilade
Term Extended:	Five years

*C.E. Van Horn*

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Charles E. Van Horn  
Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 11-44  
Rockville, MD 20857

RE: Tilade

FDA Docket No.: 93E - 0090